JUL 2 5 2001

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K010337

Proprietary Name: Lipoprint System *LDL Subfractions*

Common Name: Lipoprotein Test System (electrophoresis)

Classification Name: Electrophoretic Separation, Lipoproteins

Manufacturer:
Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach CA 90278
Phone: 310/536-0006 FAX: 310/536-9977

Contact Persons: Gebhard Neyer, Director, R&D, 310-536-0006x135

The Quantimetrix test system is substantially equivalent to other lipoprotein cholesterol tests in general use, such as the **HDL Direct Liquid Select** and the **LDL Direct Liquid Select** , sold by EQUAL DIAGNOSTICS Inc., which are supplied as liquid reagents.

The Quantimetrix Lipoprint System is supplied as a kit containing:

- 100 glass tubes with precast linear polyacrylamide gels
- Liquid loading gel with a blue lipophilic dye
- Buffer mix sufficient for approx. 7.5 l of electrophoresis buffer

The Quantimetrix product is an electrophoretic device that separates lipoproteins according to their different migration patterns. The patterns are prestained with a lipophilic dye and appear as distinctive blue bands on the electrophoresis gel. HDL migrates the fastest towards the anode. The relative distribution of total cholesterol over all the lipoprotein bands in a particular sample is determined and - using a total cholesterol value obtained from a clinically approved method - the cholesterol concentrations for all lipoprotein bands are calculated. LDL typically consists of subfractions classified as Mid-C, Mid-B, Mid-A and LDL-1 through 7. The sum of all subfractions constitutes total LDL-C. HDL is a distinctive single peak whose

cholesterol concentration constitutes the amount of HDL-C in the sample. VLDL is also a singular peak whose cholesterol concentration amounts to the VLDL-C concentration present in the sample.
The Lipoprint LDL subfraction profile for a normal population is consistent with Pattern A.

Intended Use

The Quantimetrix Lipoprint System *LDL Subfractions* ("Lipoprint System") is a device intended to measure lipoprotein cholesterol (for lipoprotein fractions and subfractions from VLDL to HDL) in fasting serum or plasma with a Total Cholesterol concentration of ≥100 mg/dl. Lipoprotein cholesterol measurements are used as an aid in evaluating lipid metabolism disorders when used in conjunction with other lipid tests, patient risk assessment and clinical evaluation.

Performance Characteristics

Accuracy

The Lipoprint System was compared to a direct HDL-C method (EQUAL Diagnostics HDL Direct Liquid Select) and a direct LDL-C method (EQUAL Diagnostics HDL Direct Liquid Select)

	Lipoprint HDL	Direct HDL
N	268	268
mean [mg/dl]	53.2	54.8
SD [mg/dl]	15.13	15.43
regression	Lipoprint HDL= 0.9361 HDL_{direct} + 1.8607	
r^2	0.912	

	Lipoprint LDL	Direct LDL
N	268	268
mean [mg/dl]	121.9	116.3
SD [mg/dl]	30.73	29.58
regression	Lipoprint LDL= 0.998 LDL_{direct} + 5.7995	
r^2	0.923	

Linearity

The Lipoprint System was found to have a linear range of 13 - 695 mg/dl for LDL, 5 - 260 mg/dl for HDL and 11 - 140 mg/dl for VLDL.

Precision

Four samples were tested for intra-assay and inter-assay variability. The selected samples:

Sample 1: low LDL-C, high HDL-C and homogeneous LDL pattern (LDL-1 and 2 only)

Sample 2: medium LDL-C, medium HDL-C and intermediate LDL pattern (LDL-1, 2 and 3)

Sample 3: high LDL, low HDL and disperse LDL pattern (LDL-1, 2, 3 and 4)

Sample 4: high LDL-C, intermed. HDL-C and disperse LDL pattern (LDL-1 through 7)

Intra-assay

Samples were tested in replicates of 12 (the maximum capacity of the electrophoresis chamber). All Midbands (C, B and A) as well as the LDL subfractions were added up to obtain the values for total LDL-C:

Sample	N	**HDL-C** Mean [mg/dl]	SD	CV [%]	**LDL-C** Mean	SD	CV [%]	**VLDL-C** Mean	SD	CV (%)
1	12	55	1.47	2.68	86	0.90	1.05	17	0.99	5.86
2	12	42	0.78	1.87	120	1.43	1.20	15	0.99	6.43
3	12	31	0.90	2.87	134	2.02	1.52	35	1.97	5.58
4	12	48	1.37	2.84	180	2.02	1.12	23	1.66	7.28

Inter-assay

Samples were tested in duplicate over 5 days, 2 runs per day, across 4 electrophoresis chambers using a single lot of gel tubes:

Sample	N	**HDL-C** Mean [mg/dl]	SD	CV [%]	**LDL-C** Mean	SD	CV [%]	**VLDL-C** Mean	SD	CV (%)
1	80	60	1.49	2.49	94	1.41	1.50	10	0.90	9.40
2	80	46	1.45	3.15	137	1.73	1.26	11	0.91	8.27
3	80	32	1.52	4.75	160	2.03	1.27	33	2.35	7.12
4	80	50	2.32	4.69	178	2.79	1.57	23	1.97	8.47

Theses data confirm that in a clinical setting the Lipoprint LDL Test System performs comparable to the EQUAL Diagnostics HDL-C Direct Liquid Select reagent and the EQUAL Diagnostics LDL-C Direct Liquid Select reagent. The device is therefore substantially equivalent to these predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 5 2001

Gebhard Neyer, Ph.D.
Director, R&D
Quantimetrix Corp.
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278

Re: 510(k) NUMBER: K010337
Trade/Device Name: Lipoprint™ System, LDL Subfractions
Regulation Number: 862.1475, 862.1660
Regulatory Class: I, reserved
Product Code: JHO, JJY
Dated: May 8, 2001
Received: May 9, 2001

Dear Dr. Neyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010337

Device Name: Lipoprint™ System, LDL Subfractions

Indications For Use:

INTENDED USE AND INDICATIONS FOR USE

The Quantimetrix Lipoprint System *LDL Subfractions* ("Lipoprint System") is a device intended to measure lipoprotein cholesterol (for lipoprotein fractions and subfractions from VLDL to HDL) in fasting serum or plasma with a Total Cholesterol concentration of ≥100 mg/dl. Lipoprotein cholesterol measurements are used as an aid in evaluating lipid metabolism disorders when used in conjunction with other lipid tests, patient risk assessment and clinical evaluation.

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010337

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)